

Application No. 10/525,783
Response dated 05/30/2006

REMARKS/RESPONSE

Amendments to the Claims:

Applicant appreciatively notes the Examiner's statement that new claims 13 - 22 were introduced (page 2 of detailed action). Applicant notes however, that in error two claims were identified as Claim 17 and thus that the highest number claim previously presented was Claim 21. Applicant respectfully requests entry of the claims as listed herein wherein the subject matter of the second "claim 17" is now presented as Claim 22.

Applicant has amended Claim 14 to limit the species therein to those corresponding to an invention of Group I as defined by the Examiner. However, in view of the remarks herein Applicant has introduced New Claim 23 dependent on Claim 13, directed to a combination as claimed in Claim 13 wherein the $\alpha 7$ -nAChR agonist is selected from the species now cancelled from Claim 14.

No new matter or any matter unsupported by the application as filed is introduced by the requested amendments.

Election/Restriction:

Applicant hereby provisionally elects, with traverse, the invention defined by the Examiner as that of Group I, that is, claims 13, 14 and 16-21 in part and Claim 15 in full, drawn to a combination of a statin and an $\alpha 7$ -nAChR agonist having a spiro-1-azabicyclo[2.2.2]octane core structure and methods for using the same.

Applicant respectfully points out that Claim 13 is a Markush-type claim having therein one explicit and one implicit Markush groups. An explicit Markush group is provided by the list of statins and an implicit Markush group is provided by the recitation of "an $\alpha 7$ -nAChR agonist." The claim is directed to a combination comprising a statin and an $\alpha 7$ -

Application No. 10/525,783
Response dated 05/30/2006

nAChR agonist. An example of such a combination would be a combination of rosvastatin and spiro[1-azabicyclo[2.2.2]octane-3,5'-oxazolidine]-2'-one.

PCT Rule concerning Unity of Invention:

First, Applicant draws the Examiner's attention to the fact that a lack of unity objection was not raised during the international phase of this application. Second, the Unity of Invention requirement under Rule 13 of the PCT is that an international application shall relate to . . . a single general inventive concept. The single general inventive concept of this application is that of a combination comprising a statin and an $\alpha 7$ -nAChR agonist. As explained in the description of this application, such combinations have the same special technical feature, namely that a "statin and an $\alpha 7$ -nAChR in combination will synergistically benefit patients suffering with neurological degenerative diseases and particularly patients suffering with Alzheimer's disease." (Description of this application, page 3, lines 2-4). Further the description discloses, "In general, it is contemplated that any statin when used in combination with any alpha-7-nAChR agonist will be useful in practicing the present invention." (Description of this application, page 9, lines 30-31).

Rule 13.2 explains further that the "special technical feature" means those technical features that define a contribution, a synergistic benefit to patients in this case, which each of the claimed inventions considered as a whole, makes over the prior art.

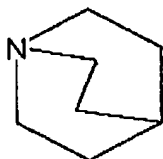
Applicant, thus, respectfully submits that the Examiner's assertion of a lack of unity is incorrect, that an invention with a single general inventive concept is claimed and that the requirement for restriction, on this basis, should be withdrawn.

35 U.S.C. § 121:

M.P.E.P. § 803.2, paragraph 3 (Rev. 3. August 2005), provides, "[b]roadly, unity of invention exists where compounds included within a Markush group (1) share a common utility, and (2) share a substantial structural feature essential to that utility. Applicant

Application No. 10/525,783
Response dated 05/30/2006

respectfully stresses that the invention of the application contemplates combination wherein a statin is used together with, i.e., combined with, an α 7-nAChR agonist. Applicant disagrees with the Examiner's assertion that α 7-nAChR agonists lack a significant shared structural element and respectfully submit that the two groups of compounds identified by the Examiner do share a substantial structural feature, namely a core structure as pictured below:



. Applicant takes the position that Claim 13, written in Markush form, encompasses a single invention, namely an invention of a combination comprising a statin and an α 7-nAChR agonist.

As regards applications that do encompass more than a single invention, M.P.E.P. § 803.2, paragraph 4 (Rev. 3. August 2005), provides, "(i)n applications containing a Markush-type claim that encompasses at least two independent or distinct inventions, the Examiner may require a provisional election of a single species prior to examination on the merits." (emphasis added). In this case Applicant strongly advocates the position that the claims of this application encompasses a single invention, namely a combination comprising a statin and an α 7-nAChR agonist. However in order to advance prosecution of this application, if the Examiner maintains the position that the claims are directed to inventions of Groups I and II, as defined by the Examiner, Applicant suggests that the Examiner should have required a provisional election of a single species for examination in accord with M.P.E.P. § 803.2.

Provisional election of a single species:

In view of the foregoing, and solely to advance prosecution of this application, if upon consideration the Examiner should decide that a provisional election of a single species is desirable to facilitate examination, Applicant provisionally elects a combination of rosvastatin and spiro[1-azabicyclo[2.2.2]octane-3,5'-oxazolidine]-2'-one as a single species of the generic invention comprising a statin and an α 7-nAChR agonist.

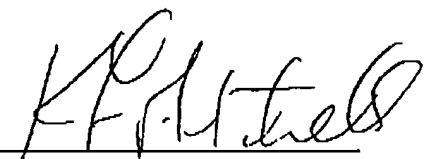
Application No. 10/525,783
Response dated 05/30/2006

Conclusion:

In view of the foregoing, Applicant respectfully requests withdrawal of the requirement for restriction and solicit prompt examination on the merits.

Respectfully submitted,

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